UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 3:23-cv-00019-RSB-JCH

DEFENDANTS' REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

For the near quarter century that mifepristone has been approved, the drug has been subject to restrictions, or "elements to assure safe use" (ETASU), to guard against risks relating to heavy bleeding, missed ectopic pregnancy, and other issues. In its most recent review, the Food and Drug Administration (FDA) found insufficient evidence to eliminate the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, including the ETASU, in its entirety.[1] Plaintiffs ask the Court to second-guess that determination, step into FDA's shoes, and effectively order the drug to be approved without a REMS (and thus without *any* ETASU). They cite no precedent for that request. And the Court should reject Plaintiffs' request because they lack standing, failed to administratively exhaust their claims, and make meritless arguments. Plaintiffs' opposition fails to show otherwise.

First, Plaintiffs decline to defend the theories of standing pleaded in their Complaint. That alone should dispose of the case. In any event, Plaintiffs' new theories and allegations fail because they are speculative, attenuated, and insufficiently supported by Plaintiffs' declarations.

Second, Plaintiffs wrongly characterize this Court's preliminary-injunction ruling on exhaustion as law of the case. This court's preliminary-injunction ruling did not create law of the case, and nothing prevents this Court from reaching a different conclusion here.

[1] As Defendants previously explained, since 2007, the ETASU have been part of mifepristone's Risk Evaluation and Mitigation Strategy (REMS). ECF No. 71-1 at 4-7.

Third, Plaintiffs' claims remain meritless. Plaintiffs do not point to any relevant statutory factor that FDA failed to consider. Instead, they claim that FDA failed to apply six factors found in a provision that the statutory text makes clear is inapplicable. They next contend that FDA failed to consider whether the drug would be safe without ETASU—that is, whether the drug's benefits would outweigh its risks. The record, however, plainly discloses that FDA found insufficient evidence that the benefits of the drug would outweigh the risks if the ETASU were eliminated. Plaintiffs also fault FDA's consideration of the alleged burdens of the ETASU without explaining how FDA could have further minimized burdens consistent with its determination that the drug has not been shown to be safe without a REMS with ETASU. Finally, Plaintiffs' criticism that FDA did not compare mifepristone to other, unrelated drugs misses the mark because the statute does not require that comparison.

Plaintiffs likewise fail to identify any relevant record evidence that FDA failed to consider. They focus on the Canadian study. But as FDA previously explained, that study was not published until 2022, after the agency completed its literature review. Nor was the study cited to the agency in connection with its REMS review even after that literature review was complete. Instead, the Canadian study was put before the agency as part of a citizen petition requesting a different agency action. And while Plaintiffs spend several pages emphasizing various kinds of evidence (surveys, declarations by litigants, advocacy statements, and data about the logistics of accessing abortion), they never squarely confront FDA's explanation that it was appropriate to focus on "objective safety data."

As to their attack on FDA's reasoning, Plaintiffs mistakenly assume that FDA was required to write on a blank slate. But the agency had already determined, on several occasions over many years, that a REMS with ETASU is necessary. Plaintiffs challenge none of those earlier decisions. Rather, the sole action Plaintiffs challenge stems from FDA's most recent review, in which the narrow question was whether evidence since 2016 was sufficient to demonstrate that FDA should depart from earlier assessments that certain ETASU are necessary. When that question is framed appropriately, the error of Plaintiffs' attacks on FDA's reasoning becomes clear.

The Court should grant Defendants' cross-motion for summary judgment.

ARGUMENT

I. Plaintiffs Lack Standing

At the outset, Plaintiffs have not met their burden of establishing Article III standing. The elements of standing—injury-in-fact, causation, and redressability—"are not mere pleading requirements but rather an indispensable part of the plaintiff's case." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Thus, "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Id.* "In response to a summary judgment motion . . . the plaintiff . . . must 'set forth' by affidavit or other evidence 'specific facts'" demonstrating standing. *Id.* (quoting Fed. R. Civ. P. 56(e)). Plaintiffs do not meet their evidentiary burden.

As Defendants explained in their motion for summary judgment, ECF No. 71-1 at 10-15, Plaintiffs' Complaint alleged only injuries to third parties (like patients and

pharmacies) and indirect injuries to themselves based on attenuated and speculative theories of causation. ECF No. 1, Compl. ¶¶ 105-118 (setting forth standing allegations). In response, Plaintiffs have abandoned the theories of standing pleaded in the Complaint, advancing new ones instead. ECF No. 74 at 15 (disavowing standing based on injuries to third parties); *id.* at 16 (identifying injuries asserted nowhere in the Complaint); *id.* at 16-17 (claiming to have standing based on direct regulation).

The Court should reject Plaintiffs' new theories and allegations. A plaintiff "may not effectively amend its Complaint by raising a new theory of standing in response to a motion for summary judgment." *La Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1089 (9th Cir. 2010); *see also United States ex rel. Owens v. First Kuwaiti General Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010) (holding that a plaintiff may not defeat summary judgment by raising allegations not contained in the complaint); *Brooks v. Receivables Performance Mgmt. LLC*, 3:21-cv-00579-RJC-DCK, 2023 WL 4228984, at *4 (W.D.N.C. Jun. 27, 2023) (holding that a plaintiff who "provide[d] no evidence in support of the injuries alleged in her Complaint" could not offer new theories); *Lawyers Comm. for 9/11 Inquiry, Inc. v. Wray*, 424 F. Supp. 3d 26, 35 (D.D.C. 2020) ("[A] plaintiff cannot use an opposition brief to amend its complaint [to allege facts supporting standing]."), *aff'd*, 848 F. App'x 428 (D.C. Cir. 2021).

In any event, the new theories are no better than the original ones.

1. Prescriber Certification. Plaintiffs' new theories challenging the prescriber certification requirement are meritless. To begin, they fail to carry their burden to show that the prescriber certification requirement causes delay in providing care. Contrary to

Plaintiffs' claims, the REMS does not require clinicians to "recertify" when they change job locations. ECF Nos. 74 at 16, 74-1 ¶ 4, 74-2 ¶ 2. Rather, the REMS directs the sponsors of mifepristone to "[e]nsure annually with each certified prescriber that their locations for receiving mifepristone are up to date." 2023 SUPP 001467. The prescriber has no duty to "recertify" before prescribing mifepristone from a new location. Absent such a duty, Plaintiffs fail to explain how the REMS delays their clinicians' patient care.

Plaintiffs also argue that the prescriber certification requirement deters other clinicians who work elsewhere from prescribing the drug, causing them to refer miscarriage patients to Plaintiffs to prescribe mifepristone off-label, which in turn leads Plaintiffs' clinicians to divert time to these patients. ECF Nos. 74 at 16, 74-1 ¶ 6, 74-2 ¶¶ 4-5, 74-4 ¶ 6. As an initial matter, any alleged injury related to mifepristone's use for an unapproved indication (miscarriage management) is simply too attenuated to establish standing to challenge restrictions related to the drug's approved use. Moreover, this theory is similar to one the Supreme Court rejected in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 390 (2024), i.e., that the plaintiffs there were injured by having to divert time to patients injured by mifepristone prescribed by other doctors. *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 390 (2024). The Court held that "[t]he causal link between FDA's regulatory actions and [the] alleged injur[y] is too speculative or otherwise too attenuated to establish standing." *Id.* at 391; *see also Clapper v. Amnesty Int'l*, 568 U.S. 398, 410 (2013) (holding that "a highly attenuated chain of possibilities" and "mere speculation" fail to satisfy the causation requirement). So too here.

2. Patient Agreement Form. Plaintiffs' novel theories regarding the Patient Agreement Form have similar flaws. ECF No. 74 at 16. Plaintiffs lack standing to seek prospective relief based on the alleged past costs of translating Patient Agreement Forms into other languages and updating software systems. *Alliance for Hippocratic Medicine*, 602 U.S. at 381 ("when a plaintiff seeks prospective relief . . . the plaintiff must establish a sufficient likelihood of future injury"). Plaintiffs do not provide evidence that they are likely to incur future costs translating the forms into additional languages. Nor is there any reason to give Plaintiffs the benefit of the doubt on that point: their declarant's statement that "the drug manufacturers do not provide the form in multiple languages" is simply incorrect.[2] ECF No. 74-1 ¶ 10. In any event, Plaintiffs identify no requirement in the REMS that they pay for such services or that their electronic systems store different templates for each clinician. *See Clapper*, 568 U.S. at 418 (holding that plaintiffs lack standing based on "self-inflicted injury"). Nor do healthcare providers have standing to challenge FDA's decisions related to approval of a drug based on the fact that patients may have questions about the drug. *See, e.g.*, *Physicians for Integrity in Medical Research, Inc. v. Hamburg*, 556 F. App'x 621, 621-22 (9th Cir. 2014) (holding that doctor lacked standing to sue FDA based on uncompensated time spent counseling patients about a drug).

[2] Danco (Mifepex sponsor), *Download Mifeprex Materials*, https://perma.cc/JE56-YYPZ (offering the form in seven languages other than English); GenBioPro (generic sponsor), *Prescriber Resources*, https://perma.cc/EML8-TUFT (offering the form in nine languages other than English).

3. Pharmacy Certification. Plaintiffs contend that "the Pharmacy Certification ETASU deters most pharmacies from dispensing mifepristone," thereby forcing Plaintiffs to dispense the drug unwillingly. ECF No. 74 at 16 (alleging that Plaintiffs "must" dispense mifepristone because of the pharmacy certification requirement). Plaintiffs allege that they would prefer not to dispense mifepristone because doing so requires them to record lot numbers and NDC numbers and incur "additional administrative work and expense." *Id.* But Plaintiffs and their declarants offer nothing more than unsupported speculation that the pharmacy certification requirement causes pharmacies in their areas not to dispense mifepristone. A pharmacy's decision not to dispense mifepristone may be driven by non-REMS factors, including state laws and moral objections of pharmacy owners.[3] Similarly, Plaintiffs cannot establish that the relief they seek would redress the harms they allege. *Alliance for Hippocratic Medicine*, 602 U.S. at 380 (explaining that redressability is the "flip side" of causation) (quoting *Sprint Commc'ns Co. v. APCC Servs., Inc.*, 554 U.S. 269, 288 (2008)). Those same non-REMS factors might cause a pharmacy to continue not dispensing mifepristone even if the pharmacy certification requirement were eliminated. *See Murthy v. Missouri*, 603 U.S. 43, 73 (2024) (finding no redressability where third-party businesses would "remain free" to continue their policies). Moreover, even if Plaintiffs could show that

[3] Indeed, when Plaintiffs filed their Complaint—the relevant time for assessing standing—non-REMS factors appear to have been determinative in at least some pharmacies' decisions not to dispense mifepristone in certain states, including Montana and Kansas. *See, e.g.*, NPR, *Walgreens won't sell abortion pills in red states that threatened legal action* (Mar. 4, 2023), https://perma.cc/KLN6-DKWK.

the pharmacy certification requirement caused pharmacies in their areas not to dispense mifepristone, that would not mean that Plaintiffs "must" do so.

4. Direct Regulation. Finally, Plaintiffs have not shown that they have standing as directly regulated parties. To establish such a theory, Plaintiffs must proffer evidence that the REMS requires or prohibits some action on their part and that they face a "substantial likelihood" of "actual or threatened enforcement" if they fail to comply. *California v. Texas*, 593 U.S. 659, 670-71 (2021). They offer no such evidence. Instead, Plaintiffs rely on non-existent requirements, the consequences of their own voluntary choices, and the alleged indirect effects of burdens on independent third parties, including patients and pharmacies. *See supra* pp. 3-8. In any event, Plaintiffs have never identified in any of their papers or declarations what enforcement they believe is substantially likely.

II. This Court's Prior Ruling On Exhaustion Is Not Law Of The Case

Rather than directly address Defendants' arguments about administrative exhaustion, ECF No. 71-1 at 15-18, Plaintiffs try to duck them by claiming that this Court's preliminary-injunction ruling is law of the case on that issue, ECF No. 74 at 18. To the contrary, the "general" rule is that "a court's decisions at the preliminary injunction phase do *not* constitute law of the case in further proceedings and do not limit or preclude the parties from litigating the merits." *Metropolitan Regional Info. Systems, Inc. v. Am. Home Realty Network, Inc.*, 948 F. Supp. 2d 538, 551 (D. Md. 2013) (citing authorities) (emphasis added). "[A] district court retains the power to reconsider and modify its interlocutory judgments . . . at any time prior to final judgment when

such is warranted." *Am. Canoe Ass'n v. Murphy Farms, Inc.*, 326 F.3d 505, 514-15 (4th Cir. 2003); *see also Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) ("[T]he findings of fact and conclusions of law made by a court granting a preliminary injunction are *not* binding at trial on the merits.") (emphasis added).

Plaintiffs rely on three wholly inapposite cases. In *Voto Latino v. Hirsch*, 1:23-cv-861, 2024 WL 2721873 (M.D.N.C. Apr. 2, 2024), the court expressly *declined* to apply law of the case. *Id.* at *2. In the other two, courts found that, in the specific circumstances of those cases, the law of the case doctrine weighed against reconsidering a merits question *that the court of appeals had previously decided* on appeal from a motion for preliminary injunction. *See L.J. v. Wilbon*, 633 F.3d 297, 308 (4th Cir. 2011); *Naser Jewelers, Inc. v. City of Concord*, 538 F.3d 17 (1st Cir. 2008). Here, by contrast, FDA has never even had an opportunity to appeal this Court's ruling on exhaustion at the preliminary-injunction stage because FDA prevailed on Plaintiffs' motion. Even under the cases Plaintiffs cite, the Court's prior ruling would not be law of the case, and—for all the reasons discussed in Defendants' opening brief, ECF No. 71-1 at 15-18—the Court should reconsider that ruling here.

III. Plaintiffs' Claims Are Meritless

If the Court reaches the merits, it should grant summary judgment against Plaintiffs' Administrative Procedure Act challenge to FDA's 2023 decision to retain a modified version of the Mifepristone REMS Program. In that decision, FDA applied the modification standard in 21 U.S.C. § 355-1(g)(4)(B) and found insufficient evidence to conclude that mifepristone would be safe (i.e., that its benefits would outweigh its risks)

without the prescriber certification requirement, Patient Agreement Form, and pharmacy certification requirement. The merits of Plaintiffs' challenge turn on whether FDA acted within its statutory authority, 5 U.S.C. § 706(2)(C), "examine[d] all relevant factors and record evidence," and "articulate[d] a reasoned explanation for its decision." *Am. Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983)). It did.

A. Staying within its statutory authority, FDA considered all relevant factors

Section 355-1(g)(4)(B) provides that "[a]fter the approval of a [REMS]," FDA "may" require the sponsor of the drug to "submit a proposed modification" if, as relevant here, FDA "determines that 1 or more goals or elements should be added, modified, or removed" to (1) "ensure the benefits of the drug outweigh the risks of the drug" or (2) "minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B). A REMS is "part of [an] application" that must be approved under § 355. *Id.* § 355-1(a). FDA cannot approve a new drug application unless the drug is shown to be safe and effective for its intended use. *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). Similarly, when a drug's sponsor proposes changes to the drug's conditions of approval (including changes to the REMS), FDA reviews the scientific evidence submitted in support of the proposal to determine whether the drug would continue to be safe and effective with the proposed changes. *See* 21 C.F.R. § 314.70. And in determining whether a drug is "safe," FDA examines

whether "the benefits of the drug outweigh its risks." FDA Guidance for Industry, *Benefit-Risk Assessment for New Drug and Biological Products* (Oct. 2023).[4]

Largely ignoring the REMS modification and drug approval standards of §§ 355-1(g)(4)(B) and 355(d), Plaintiffs accuse FDA of failing to consider factors that either are irrelevant or were in fact considered by FDA.

1. The § 355-1(a)(1) factors. FDA's initial decision to require the sponsor of a pending application to propose a REMS is governed by § 355(a)(1), which lists six specific factors for FDA to consider. But § 355-1(g)(4)(B) neither contains those factors nor cross-references § 355-1(a)(1). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Thus, contrary to Plaintiffs' contentions, *see* ECF No. 74 at 3-4, the statutory text is clear that the § 355-1(a)(1) factors do not apply to REMS modifications.

Plaintiffs fault FDA for citing the heading of 355-1(a)(1) (which indicates that the provision applies to "Initial Approval") as if that were FDA's only argument. ECF No. 74 at 3. But that is only one of the many textual signs that point against reading the subsection (a)(1) factors into subsection (g)(4)(B). For one thing, the only cross-reference to subsection (a)(1) anywhere in § 355-1 repeats the language in subsection (a)(1)'s heading. 21 U.S.C. § 355-1(h)(3) (referring to a REMS "submitted under subsection (a)(1)

[4] Available at https://www.fda.gov/media/152544/download (accessed Mar. 18, 2025).

in an application for initial approval"). Moreover, subsection (g)(4)(B) expressly applies "*[a]fter the approval* of a REMS." 21 U.S.C. § 355-1(g)(4)(B) (emphasis added). By contrast, subsection (a)(1) applies *before* approval, when the REMS is still "*proposed*." *Id.* § 355-1(a) (emphasis added). What is more, the dispute resolution procedures for reviewing determinations under subsection (a)(1) are different from the dispute resolution procedures for reviewing determinations under subsection (g)(4)(B). *See* 21 U.S.C. § 355-1(h)(3), (4). And finally, the factors in subsection (a) are crafted in language that more naturally applies to drugs that have not previously been marketed for a particular use subject to a REMS. ECF No. 71-1 at 29 (discussing 21 U.S.C. § 355-1(a)(1)(A)-(F)).

Despite all of this, Plaintiffs suggest that because both subsection (a)(1) and subsection (g)(4)(B) use the word "determine," the factors in subsection (a)(1) must be considered in subsection (g)(4)(B). ECF No. 74 at 4. While both provisions use the word "determine," only subsection (a)(1) directs FDA to consider six specific factors. FDA does not dispute that, in determining whether to modify the REMS, FDA must make an "assessment" of whether evidence supports departing from the agency's conclusion that "the drug's risks require [a] REMS." *Washington v. FDA*, 668 F. Supp. 3d 1125, 1140 (E.D. Wa. 2023). But in making that assessment, FDA need not consider factors that are nowhere mentioned or cross-referenced in subsection (g)(4)(B).

2. The necessity of ETASU. Contrary to Plaintiffs' assertion, *see* ECF No. 74 at 4, FDA considered whether mifepristone "can be approved only if, or would be withdrawn unless," such ETASU are included. 21 U.S.C. § 355-1(f)(1)(A). FDA has approved mifepristone only *with* restrictions to assure safe use. The relevant question in

determining whether to modify the Mifepristone REMS Program, therefore, was whether the agency could now approve mifepristone *without* ETASU. To repeat: FDA may not approve an application to modify the conditions of approval for a drug unless the agency is satisfied that the evidence shows that the drug will be safe (i.e., that its benefits will outweigh its risks) with the modification. *Id.* §§ 355-1(g)(4)(B), 355(d); 21 C.F.R. §§ 314.1 (providing that new drug application requirements apply to supplemental applications), 314.105(c). Here, FDA found insufficient information to depart from its prior conclusions to find that mifepristone's benefits would outweigh its risks if the REMS with ETASU were eliminated. 2021 REMS 001574, 1578, 1597.

3. Burdens on patients. Plaintiffs' argument that FDA failed to consider burdens on patients is fundamentally misconceived. ECF No. 74 at 4-6. Nothing in the statute requires FDA to reduce the burden of ETASU on patients when FDA determines that it cannot be done safely. FDA noted that it had already minimized the burden on the prescriber certification requirement, 2021 REMS 001574, 1597, and Plaintiffs identify no way that FDA could have further minimized the burden on patients in a manner consistent with the agency's finding that the evidence was insufficient to show that the drug's benefits would outweigh its risks without a REMS with ETASU.

4. **Comparison to other drugs.** Plaintiffs clarify that they do not contend that FDA ignored the requirements of § 355-1(f)(2)(D). ECF No. 74 at 14-15. That provision contemplates comparing mifepristone to drugs with ETASU intended to mitigate against risks that are not only "serious" but "similar" to those of mifepristone. 21 U.S.C.

§ 355-1(f)(2)(D). Plaintiffs do not identify any such drug with risks "similar" to those of mifepristone that FDA failed to consider.

Nevertheless, citing *Kirk v. Comm'r of Soc. Sec. Admin.*, 987 F.3d 314 (4th Cir. 2021), Plaintiffs contend that it was arbitrary and capricious for FDA not to consider other drugs that do not have ETASU and fall outside the ambit of § 355-1(f)(2)(D). *Kirk* observes that "[a] fundamental norm of administrative procedure requires an agency to treat like cases alike." *Id.* at 321. Here, the statutory provision that Plaintiffs admit does not apply specifies the relevant reference point: drugs with "similar, serious risks." 21 U.S.C. § 355-1(f)(2)(D). It would make no sense for Congress to say so if Congress shared Plaintiffs' view that FDA must compare mifepristone to drugs with all sorts of *other* risks.

B. FDA considered all relevant evidence

As explained above, in applying the REMS modification standard's benefit/risk framework, FDA looked to whether "evidence" since 2016 demonstrates that the ETASU could be eliminated. FDA considered all relevant evidence that was before the agency in its REMS review. Plaintiffs fail to show otherwise.

1. Canadian study. As FDA explained (ECF No. 71-1 at 17-18, 34-35), the Canadian study (2022 CP 000099-109) was not before FDA at the time that FDA conducted its comprehensive literature review. Nor did anyone urge FDA to consider that study in connection with the decision under review in this case. *Id.* Instead, the Canadian study was submitted to FDA after the close of its literature review as part of a citizen petition that requested a different agency action and made arguments outside

the scope of this case. *Id.* Plaintiffs cite no authority supporting their contention that FDA was required to pluck this study out of the record for that separate action and consider it *sua sponte* here.

Plaintiffs insist that FDA must have been "aware" of the study at the time of the January 2023 REMS Modification because the agency denied the citizen petition in which the study was cited on the same day as that decision. ECF No. 74 at 7. But the point of having a cut-off date for FDA's literature review was that the agency would not have to endlessly delay a final decision when new studies were published in the year-long interval between when FDA directed the sponsors to propose modifications to the REMS and FDA's approval of those modifications. *Cf. Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 554–55 (1978) ("there would be little hope that the administrative process could ever by consummated" if an agency were required to consider any evidence that arrives in the "gap between the time the record is closed and the time the administrative decision is promulgated") (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944)).

To be sure, FDA reviewed certain materials after the cut-off date when those materials came to its attention *in connection with its review of the proposed modifications*. For example, FDA reviewed materials cited by the *Alliance for Hippocratic Medicine* plaintiffs in their November 2022 preliminary-injunction motion, which argued, among things, that the in-person dispensing requirement remained necessary—an issue that went to FDA's forthcoming January 2023 REMS Modification. The published Canadian study, by contrast, was not cited in any challenge to that forthcoming action. Rather, the

primary request of the citizen petition in which the Canadian study was cited was for FDA to direct the sponsor of Mifeprex to submit a supplemental application seeking approval of mifepristone for miscarriage management. 2022 CP 000071-81. The Canadian study was cited in connection with a secondary request in that petition to modify the REMS so that it would not be unduly burdensome *for that new indication*. 2022 CP 000081, 87. Ultimately, the citation was irrelevant to FDA's disposition of the petition: FDA determined that it was up to the sponsor to decide what indications to seek approval for. 2022 CP 000111-113.

2. Other evidence. FDA appropriately considered the remaining evidence, focusing primarily on "objective safety data," ECF No. 71-1 at 32-33, that is, "publications containing safety data related to the outcomes of medical abortion," 2021 REMS 001571. In fact, Plaintiffs identify no "objective safety data" that FDA did not review. Instead, Plaintiffs allege that FDA failed to consider various surveys, litigation declarations, advocacy statements, and data about the logistics of accessing abortion. ECF No. 74 at 8-11. As FDA explained in its opening brief, the agency generally determined that such material was not informative in FDA's safety analysis, though the agency did consider the material. ECF No. 71-1 at 32-34. Plaintiffs do not address FDA's point that "objective safety data" is most germane.

Plaintiffs' reliance on *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020), is misplaced. That case (unlike this one) involved notice-and-comment rulemaking, in which the agency has a particular obligation to respond to "relevant" and "significant" public comments. *Catholic Legal Immigration Network, Inc. v. Executive Office for*

Immigration Review, 513 F. Supp. 3d 154, 173 (D.D.C. 2021) (quoting *Home Box Office, Inc., v. FCC*, 567 F.2d 9, 35 & n.58 (D.C. Cir. 1977)). *Mayor of Baltimore* stands only for the proposition that an agency cannot disregard relevant comments without response. It does not obligate FDA, in reviewing safety outside the context of rulemaking, to agree with Plaintiffs that advocacy statements are relevant.

C. FDA offered a reasoned explanation for its decision

FDA's determination not to eliminate the ETASU—and its explanation for that decision—was eminently reasonable considering the context. In its 2021 REMS review, FDA did not make a *de novo* assessment of whether ETASU are necessary for mifepristone. Rather, FDA undertook its review against the backdrop of its prior determinations that mifepristone's benefits had not been shown to outweigh its risks without ETASU. Importantly, Plaintiffs *do not challenge* those prior determinations in this litigation, including FDA's approval decision in 2000; Congress's decision in 2007 to "deem" existing restrictions on drugs such as mifepristone to be a REMS with ETASU; and FDA's affirmation in 2011 and 2016 that the safe-use restrictions on mifepristone could not be eliminated.

Rather than retread old ground, FDA asked whether evidence since the last of these actions in 2016 justified a change that would result in the elimination of all ETASU. After all, FDA cannot approve a supplemental application modifying the conditions of approval for a drug if the information before FDA is "insufficient" to show that the drug is safe and effective under those modified conditions. 21 U.S.C. § 355(d); *see also* 21 C.F.R. §§ 314.50, 314.105(c). This requires a "demonstration" of safety.

See supra pp. 10-11 (citing Guidance). Here, FDA explained that the required demonstration had not been made because the evidence—primarily "objective safety data"—did not provide the agency with the assurance it would need to change its baseline assessment and remove all restrictions. And the agency proceeded, ETASU-by-ETASU, to explain the evidentiary gaps that led it to its decision to require pharmacy certification and not eliminate the prescriber certification and Patient Agreement Form ETASU. That explanation is set forth in a 40-page memorandum in the administrative record. ECF No. 71-1 at 19-23; 2021 REMS 001561-1608.

Plaintiffs spend several pages of their brief (ECF No. 74 at 11-14) disagreeing with FDA's reasoning, but their critiques incorrectly put the onus on FDA to re-justify the ETASU as if this were a *de novo* assessment. *See, e.g.*, ECF No. 74 at 11 (dismissing FDA's baseline assessment as "groundless assumptions"); *id.* at 12 (criticizing FDA's starting "assumption" that the prescriber certification requirement is necessary); *id.* (faulting FDA for citing "absence of evidence" of safety as a reason for maintaining prescriber certification); *id.* (demanding that FDA point to "new safety issues" to justify maintaining prescriber certification); *id.* at 13 (criticizing FDA's "assumption" that prescriber certification ensures prescribers will continue to have the requisite qualifications); *id.* at 13-14 (criticizing FDA's "assumption" that the Patient Agreement Form provides necessary assurance that prescribers will fully inform patients of the risks of mifepristone). What Plaintiffs call "assumptions" are in fact prior determinations resulting from previous agency actions going back nearly 25 years—none of which Plaintiffs challenge.

Once Plaintiffs' misunderstanding of the nature of FDA's review is corrected, it is apparent that FDA engaged in reasoned decision-making. And there is no dispute that, when it comes to FDA's safety determinations about drugs, FDA is entitled to the utmost deference. ECF No. 74 at 1 (acknowledging that FDA is entitled to deference if it engaged in reasoned decision-making); *Balt. Gas. & Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982). As the Chief Justice admonished the last time a district court ordered FDA not to enforce a mifepristone ETASU, the "significant deference" due to the agency in this area should make courts reluctant to "compel the FDA to alter the regimen for medical abortion." *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S.Ct. 578, 579 (2021) (Roberts, C.J., concurring in the grant of application for stay).[5]

IV. If Plaintiffs Prevail, The Court Should Order Separate Briefing On Remedy

Defendants requested in their opening brief that the Court order separate briefing on remedy if Plaintiffs prevail. ECF No. 71-1 at 35-36. Plaintiffs do not oppose that request, but state that they believe vacatur to be the appropriate remedy. The plaintiffs in *Washington* sensibly declined to request vacatur, realizing that that relief could potentially open the door to disruptive consequences. Plaintiff States' Motion for Summary Judgment, *Washington v. FDA*, 1:22-cv-3026-TOR, ECF No. 156 at 25 (Oct. 10, 2024). Rather than risk those consequences, the Court should invite the parties to express their views on remedy only if the Court grants Plaintiffs' motion for summary

[5] In a footnote, Plaintiffs oppose granting Defendants summary judgment on Plaintiffs' constitutional claims. ECF No. 74 at 15 n.4. They concede that rational-basis review applies but deny that FDA has a rational basis for requiring ETASU. For the reasons explained above, that is wrong.

judgment, in which case the parties will be able to tailor their arguments about remedy to any injuries and violations the Court believes exist.

At this stage, it is enough to note that Plaintiffs do not explain how vacatur of FDA's 2023 decision—the only agency action they challenge—would redress their alleged injuries. The normal effect of vacatur is to "restore the status quo ante." *Sierra Club v. Johnson*, 374 F. Supp. 2d 30, 32-33 (D.D.C. 2005). Here, the immediate status quo ante consisted of restrictions on mifepristone that were *more* stringent than the current restrictions, and there was never a status quo ante in which mifepristone was approved with *less stringent* safe-use restrictions. *See Washington*, 668 F. Supp.3d at 1143 ("[E]njoining the 2023 REMS and returning to the status quo would eliminate the ability of pharmacies to provide the drug, thereby reducing its availability. This runs directly counter to Plaintiffs' request.")

It is evident that by "vacatur" Plaintiffs mean something different than simply setting aside the agency action they challenge. Rather, Plaintiffs seem to request that the Court not only vacate the challenged agency action, but order that the drug be deemed approved *without* a REMS—despite the fact that FDA has never found the drug safe and effective under those conditions. They cite no authority for the Court to do that. But there is no need to consider the question of remedy unless the Court finds fault with FDA's decision-making, at which time the parties will be able to brief the issue fully.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' cross-motion for summary judgment.

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CERTIFICATE OF SERVICE

I hereby certify that, on March 18, 2025, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen
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